

AUG 1 4 2001

K010399
p1/2

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): Diatek
101 N. Chestnut St.
Winston-Salem, NC 27101

Phone: 336-725-9711
Fax: 336-725-0035

Contact Person: Todd Cassidy

Date of Summary: January 19, 2001

Trade Name: Diatek Cannon-Cath

Classification Name: Catheter, Hemodialysis, Implanted

Predicate Device: Medcomp Ash Split-Cath 28cm and 32cm K972207

Intended Use:

The Diatek Cannon-Cath is designed for chronic hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the jugular vein. Although this catheter may be inserted into the subclavian vein, the jugular is the preferred site.

The Cannon-Cath is intended for use in adult patients.

Device Description:

The Diatek Cannon Catheter consists of a double lumen catheter with a detached connector assembly. This allows the catheter tip to be precisely positioned within the vein, similar to single lumen, dual catheters. After the catheter has been positioned, the proximal end of the catheter is tunneled retrograde to the exit site. The connector assembly is then fastened to the proximal end of the catheter using a compression sleeve and compression cap.

Testing:

The Diatek Cannon Catheter has been tested by both internal and outside laboratories for a wide range of criteria as well as in comparison to the predicate device. These reports are included in sections 10 and 11

	Diatek Cannon Catheter	MedComp AshCath Predicate Device I
Indications for use	Equivalent	Long Term Hemodialysis and Apheresis
Where Used: hospital home, ambulance, etc.	Equivalent	The catheter will be implanted in the operating room. This is a sterile environment. Long-term, the catheter will be used in the Dialysis centers. Standard treatment centers are generally outside the hospital setting and are non-sterile environments.
Patient Population	Equivalent	Adult Patients
Design Materials		
Luer Hubs	Polyurethane	Nylon
Access Lines	Polyurethane	Polyurethane
Clamps	Polypropylene	Polypropylene
Y fitting	Polyurethane	Polyurethane
Compression Cap	Polyurethane	N/A
Catheter Body	Polyurethane	Polyurethane
Cuff	Polyester fiber	Polyester fiber
Compression Sleeve	Silicone	N/A
Connecting Tubing	SS Hypo Tubing	N/A
Physical Characteristics		
Catheter type	Dual Lumen	Dual Lumen
Shape of lumens	Double D	Double D
OD	0.2	0.19
Available Lengths	24, 28, 32, 36 cm	24, 28, 32, 36 cm
Number of lumens	2	2
Dilator/Sheath Size	16 FR	16 FR
Sterility		
Method of sterilization	EtO	EtO



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2001

Mr. Todd Cassidy
Executive Vice President
Diatek, Inc.
101 N. Chestnut Street
Winston-Salem, North Carolina 27101

Re: K010399
Diatek Cannon-Cath
Regulation Number: 21 CFR §876.5540
Regulatory Class: III
Product Code: 78 MSD
Dated: May 16, 2001
Received: May 30, 2001

Dear Mr. Cassidy:

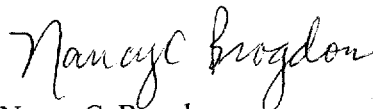
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Nancy C. Brogdon".

Nancy C. Brogdon
Director, Division of Reproductive
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010399

Device Name: Diatek Cannon-Cath

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010399